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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,978	11/14/2003	Michael B. Yaffe	01997/545003	5853

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,978	YAFFE ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-38 are pending in the application.

Election/Restrictions

[3] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a computer comprising structural coordinates of a Polo-box domain, classified in class 345, subclass 419.

II. Claim 2, drawn to a computer comprising a pharmacophore model of a phosphopeptide that binds a Polo-box domain, classified in class 345, subclass 419.

III. Claim 3, drawn to a method of selecting or designing a candidate ligand for a Polo-box domain, classified in class 702, subclass 27.

IV. Claims 4-9, drawn to a crystal of a Polo-like kinase complex and an isolated fragment of a Polo-box domain in complex with a phosphopeptide, classified in class 435, subclass 194.

V. Claims 10-12, drawn to a phosphopeptide that optionally binds human Plk-1, classified in class 530, subclass 350.

VI. Claims 13-16, drawn to a method for treating or inhibiting a cellular proliferative disorder, classified in class 514, subclass 2.

VII. Claims 17-18, drawn to a method for identifying a peptidomimetic compound that modulates Polo-like kinase biological activity, classified in class 435, subclass 15.

VIII. Claims 19-22 and 35-36, drawn to a method to identify phosphopeptide or non-phosphopeptide binding modules, classified in class 435, subclass 7.1.

IX. Claims 23-29, drawn to a degenerate phosphopeptide that binds a tandem BRCT domain, a phosphopeptide binding module comprising a BRCT tandem domain, and a complex thereof, classified in class 530, subclass 350.

X. Claims 30-31, drawn to a method for identifying a candidate compound for the treatment or prevention of a neoplasia, classified in class 435, subclass 7.1.

XI. Claims 32-34, drawn to a method for identifying a peptidomimetic compound that modulates BRCT biological activity, classified in class 435, subclass 7.1.

XII. Claims 37-38, drawn to a modified peptide, classified in class 530, subclass 350.

[4] The inventions are distinct, each from the other because:

[5] The inventions of Groups I and II are directed to related computers. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the computers of Groups I and II comprises distinct structural coordinates and neither of the computers is an obvious variant of the other.

[6] Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the phosphopeptide of Group V is not the same as the phosphopeptide of the complex. The subcombination has separate utility such as being used to treat or inhibit a cellular proliferative disorder.

[7] The inventions of Groups IV-V, IX, and XII are directed to peptides or polypeptides. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the peptides or polypeptides of Groups IV-V, IX,

and XII is structurally distinct and no single peptide or polypeptide of Groups IV-V, IX, and XII would render any of the others obvious to one of ordinary skill in the art.

[8] The computers of Groups I-II, the crystal of Group IV, and the peptides or polypeptides of Groups V, IX, and XII are distinct entities capable of separate manufacture, use, and effect.

[9] The computer of Group I and the method of Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the computer of Group I can be used for word processing.

[10] The computer of Group I is unrelated to the methods of Groups VI-VIII and X-XI as it is neither made nor used by the methods of Groups VI-VIII and X-XI.

[11] The computer of Group II, the crystal of Group IV, and the modified peptide of Group XII are unrelated to the methods of Groups III, VI-VIII, and X-XI as they are neither made nor used by the methods of Groups III, VI-VIII and X-XI.

[12] The phosphopeptide of Group V is unrelated to the methods of Groups III and X-XI as it is neither made nor used by the methods of Groups III and X-XI.

[13] The phosphopeptide of Group V and the methods of Groups VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can

be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the phosphopeptide of Group V can be used for producing the crystal of Group IV.

[14] The phosphopeptide of Group IX is unrelated to the methods of Groups III and VI-VII as it is neither made nor used by the methods of Groups III and VI-VII.

[15] The phosphopeptide of Group IX and the methods of Groups VIII and X-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the phosphopeptide of Group IX as an antigen for the production of an antibody.

[16] The methods of Groups III, VI-VIII, and X-XI are unrelated as they comprise different method steps, utilize different products, and yield different results.

[17] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-XII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In view of the recited limitations of the claims of each invention, a separate sequence and patent and

non-patent literature search for each Group is required. As such, co-examination of the inventions of Groups I-XII would require a serious burden on the examiner.

[18] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[19] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[20] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656